BD Medical
1 Becton Drive
Franklin Lakes, New Jersey 07417
tel: 201.847.6800
fax: 201.847.4896
www.bd.com

K100209

FEB 19 2010

BD

Helping all people live healthy lives

510(K) SUMMARY

Date of Summary Preparation: January 22, 2010

1. **Submitted By:**

Pasquale Amato
Senior Regulatory Affairs Specialist

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

Phone: 201-847-4513
Fax: 201-847-5307

Contact Person:
Eileen Hiller
Manager, Regulatory Affairs
Phone: 201-847-4570
Fax: 201-847-5307
Email: Eileen_Hiller@BD.com

2. **Device Name:**

Trade Name:	BD Eclipse™ Needle with SmartSlip™ Technology
Common Names:	Eclipse Hypodermic Needle
Classification Name:	Needle, Hypodermic, Single Lumen
Classification:	Class II, 21 CFR 880.5570 FMI

3. **Predicate Device:**

BD Eclipse™ Hypodermic Needle- K010188 and K043397

Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

The BD Eclipse™ Hypodermic Needle (BD Eclipse™ Hypodermic Needle 510(k): K010188 and K043397 with the metal clip) is a device that is composed of a typical hypodermic needle with a one-piece hub/adapter and pivoting safety cover that is connected to the adapter. The metal clip is inserted into the hub to minimize the incidence of needle detachment from a luer slip tip syringe.
The modified device, BD Eclipse™ Needle with SmartSlip™ Technology, has the same characteristics as the predicate devices except for the clip in the hub. The material of the clip has been changed from metal to plastic. The function of the plastic clip remains the same as the metal. When assembled into the hub, the clip ensures that the needle is attached to a luer slip syringe with sufficient force by the user. The pivoting safety cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal.

The basic needle dimensions (diameter, injection length, needle tip geometry, materials and lubrication) are the same for the BD Eclipse™ Needle with SmartSlip™ Technology modified device, the standard BD Hypodermic Needle and the predicate device BD Eclipse™ Hypodermic Needle with the metal clip.

5. **Intended Use:**

The BD Eclipse™ Needle with SmartSlip™ Technology is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse™ Needle with SmartSlip™ Technology is compatible for use with standard luer-slip and luer-lock syringes.

The BD Eclipse™ Needle with SmartSlip™ Technology contains a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Technological Characteristics:

The principal device of this premarket notification is the result of a design change to the predicate device (K043397) conducted in accordance with Quality System Regulations. The BD Eclipse™ Needle with SmartSlip™ Technology, modified, is equivalent to the predicate devices, the BD Eclipse™ Hypodermic Needle (K010188 and K043397) given that:

The principal device has the same hypodermic needle cannula as the predicate BD Eclipse™ Hypodermic Needle.

R

The principle device has the same safety components and assembly as the predicate BD Eclipse™ Hypodermic Needle.
The principal device has the same intended use and indications for use as the predicate device.
The devices are manufactured from the same materials.
The devices are sterilized with SAL of 10^{-6}.
The devices operate under the same principles.

The only difference between the The BD Eclipse™ Needle with SmartSlip™ Technology, modified, and the predicate device is the material of the clip in the hub.

6. **Performance:**

Bench tests relating to the performance of the The BD Eclipse™ Needle with SmartSlip™ Technology were conducted.
The principal device demonstrated equivalent performance to the predicate device during bench testing. Bench testing consisted of:

i. Clip engagement force – must meet force requirements as specified in the product specification
ii. Snap Clip Drop Test – clip must remain intact in the hub

The results of these tests demonstrate that the The BD Eclipse™ Needle with SmartSlip™ Technology, modified, perform equivalent to the predicate device and is safe and effective when used as intended.

R

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 19 2010

Mr. Pasquale Amato
Senior Regulatory Affairs Specialist
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K100209
Trade/Device Name: BD Eclipse™ Needle with SmartSlip™ Technology
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 22, 2010
Received: January 25, 2010

Dear Mr. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: BD Eclipse™ Needle with SmartSlip™ Technology

Indications For Use:

The BD Eclipse™ Needle with SmartSlip™ Technology is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse™ Needle with SmartSlip™ Technology is compatible for use with standard luer-slip and luer-lock syringes.

The BD Eclipse™ Needle with SmartSlip™ Technology contains a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

R

510(k) Number: K100209

000022